January 31, 2025

Innovate Orthopaedics Ltd
Mike Bilson
QA/RA Manager
The Globe
Bridge Street
Slaithwaite, Huddersfield, West HD7 5JN
United Kingdom

Re: K242442
Trade/Device Name: Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 12, 2024
Received: August 16, 2024

Dear Mike Bilson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242442

Device Name

Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw

Indications for Use *(Describe)*

Quick-Start Screws are indicated for interference fixation of grafts for ligament reconstruction such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) #: K242442

510(k) Summary

Prepared on: 2025-01-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Innovate Orthopaedics Ltd
Applicant Address	The Globe Bridge Street Slaithwaite, Huddersfield West Yorkshire HD7 5JN United Kingdom
Applicant Contact Telephone	01484 796796
Applicant Contact	Mr. Mike Bilson
Applicant Contact Email	mike.bilson@innovateortho.co.uk

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Quick-Start Orthopaedic Fixation Screw and Reverse Thread Screw
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231819	Quick-Start Orthopaedic Fixation Screw and Reverse Thread Scre	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The Innovate Orthopaedics Quick-Start Orthopaedic Fixation Screw family of products are interference screws indicated for the fixation of grafts in ligament reconstruction procedures such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions. The screw is composed of medical grade titanium alloy and is supplied sterile for single use in both standard thread and reverse thread designs.

Accessory Descriptions
The Innovate Orthopaedics Quick-Start Guide-Wire accessory is composed of medical grade nickel-titanium alloy and is supplied sterile for single use. The Guidewire is 1.8mm in diameter and 250mm in length.

The Innovate Orthopaedics Quick-Start 3.5 Hex Cannulated Screwdriver is composed of a highgrade stainless-steel shaft with a silicon rubber soft-grip handle. The screwdriver is supplied non-sterile and is cleaned and sterilized at the customer facility.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Quick-Start Screws are indicated for interference fixation of grafts for ligament reconstruction such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device indications are as follows:

Quick-Start Screws are indicated for interference fixation of grafts for ligament reconstruction such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions.

The indications for the predicate device are as follows:

Quick-Start Screws are indicated for interference fixation of soft tissue grafts and/or bone-tendon-bone grafts for ligament reconstruction such as anterior/posterior cruciate ligament (ACL/PCL), medial collateral (MCL), lateral collateral (LCL), posterolateral corner (PLC) and medial patellofemoral (MPFL) reconstructions.

The only difference in indications for the subject device compared to the predicate device, is to remove mention of specific grafts as these are not applicable to an indication statement. There is no actual change in device indications.

Therefore the change in wording for the subject device is considered to be the same intended use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Technological characteristics of the subject device are unchanged from the previously cleared Quick-Start Orthopaedic Fixation Screws (K231819):
The following are the key technological characteristics of the devices:
- Manufactured from Titanium Ti6-AL4-V ELI alloy per ASTM F-136.
- The driver interface of 3.5 mm hex.
- Cannulated for use with guide wire accessories.
- Variable, or graduated, lead in thread to ease insertion.
- The head has a flat beveled edge head profile with a thread starter marker.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The subject device is identical to the currently legally marketed Quick-Start Screws, in physical form therefore the bench testing submitted in previous 510(k)s (K231819 & K212547), remains applicable to the subject device.

Bench testing applicable to the additional provision for use in fixation of synthetic grafts is included in the current submission. Fixation strength testing of various sizes of synthetic grafts with the Quick-Start Screws was performed. This demonstrated sufficient fixation strength to meet the minimum clinical requirement for the intended function of the synthetic grafts. The intended function of the synthetic grafts are as a reinforcement of the soft tissues repaired by suture or other fixation devices.

The bench testing performed supports the conclusion that the Quick-Start Screws may be used effectively to fixate synthetic grafts within the device indications, and such use does not introduce any new questions of safety or performance and the Quick-Start Screws with this provision are as safe and effective as the currently legally marketed Quick-Start Screws.